

## UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,901	02/09/2001	Charlene A. Boehm	46607-248184	6758
7590 09/09/2004			EXAMINER	
J. Michael Boggs Kilpatrick Stockton LLP			MARSCHEL, ARDIN H	
1001 West Fou			ART UNIT	PAPER NUMBER
Winston-Salem, NC 27101-2400			1631	
			DATE MAILED: 09/09/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Summany	09/780,901	BOEHM, CHARLENE A.				
Office Action Summary	Examiner	Art Unit				
TI. MAU INO DATE COLO	Ardin Marschel	1631				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 6/9/04.						
	2a)☑ This action is <b>FINAL</b> . 2b)☐ This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
<ul> <li>4)  Claim(s) 1.2 and 4-29 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1.2 and 4-29 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>						
Application Papers						
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
		•				
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> <li>Paper No(s)/Mail Date</li> </ol>	4)  Interview Summary (F Paper No(s)/Mail Date 5)  Notice of Informal Pat 6)  Other:	e. <u>5/11/04</u> .				

Application/Control Number: 09/780,901

Art Unit: 1631

## **DETAILED ACTION**

Applicants' arguments, filed 6/9/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

## LACK OF ENABLEMENT

Claims 1, 2, and 4-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in <a href="Exparte Forman">Exparte Forman</a>, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in <a href="In re Wands">In re Wands</a>, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Application/Control Number: 09/780,901

Art Unit: 1631

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

This rejection is maintained and reiterated from the previous office action, mailed 3/9/04. In REMARKS, filed 6/9/04, starting on page 14 therein applicant summarizes various claim limitations and bases for this rejection. On page 15, last two lines, arguments start with an allegation that wavelength based on length of a genomic material can be considered as having a resonant frequency and that that length may be measured for biomolecular chains of DNA or RNA. This is an allegation without factual basis which does not include consideration of the coiled etc. complexity of such DNA or RNA in genomic material. This is in contrast to the basis for this rejection set forth in the office action, mailed 3/9/04, which has set forth antenna considerations such as its configuration, for example, coiled, etc. which do, in fact, significantly affect the resonance frequency of any material which may receive or absorb electromagnetic energy. Allegations are insufficient to overcome factual basis as set forth in said previous office action. Applicant then argues that the complexity of genomic material in a living cell is merely addressed by multiplying the base pair number by the average spacing between base pairs. Again this allegation ignores the factual basis for this rejection that the base pairs in the genomic material in a living cell is not additively lined up to result in a length such a linear antenna for receiving electromagnetic energy. Thus, this argument is non-persuasive as being another allegation without factual support which does not negate the basis for this rejection as set forth in said previous

Application/Control Number: 09/780,901

Art Unit: 1631

office action. Applicant then argues that the determination of frequencies is instantly set forth for example microorganisms. It is acknowledged that the non-enabled calculations of wavelength are set forth instantly but with the above summarized simplistic assumptions as to a corresponding resonant frequency. The calculation of a theoretical wavelength via an unpredictable methodology which ignores factors of antenna shape in such wavelength calculations is not persuasive to overcome this rejection. Applicant then argues that several field demonstrations selectively influence a target genomic material in a desired manner and admit that this has occurred "whether or not "resonance" of the genomic material is achieved". Thus, applicant admits that resonance has not been predictably determined or demonstrated in such field demonstrations. Also, it is noted that selectively has not been determined or demonstrated either as argued. Generic electromagnetic energy application to materials is well known to cause heating in many situations, but such generic heating via energy application is not known to be a resonance effect nor mediated due to some type of wavelength which is selectively characteristic of material, such as genomic material. Applicant also argues that predictability of resonance is not a factor influencing enablement of the claimed invention. This argument is directly contrary to the claim wording which clearly sets forth first and second resonant frequencies and therefore non-persuasive as being contrary to the factual basis of the claim wording. In summary, this rejection still is deemed proper.

No claim is allowed.

Art Unit: 1631

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 6, 2004

ARDIN H. MARSCHEL FRIBARY EX MILLER